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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,420	04/05/2001	James E. McGowan, JR.	1489.1001	5040
21171	7590	07/01/2004	EXAMINER	
STAAS & HALSEY LLP SUITE 700 1201 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			CHORBAJI, MONZER R	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/826,420

Applicant(s)

MCGOWAN,, JAMES E.

Examiner

MONZER R CHORBAJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This non-final office action is in response to the RCE received on 05/04/2004

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 33, line 9; applicant uses the phrase "without a ported nozzle", however, the specification and the drawings does not teach such a limitation. On page 12 of the Remarks section of the amendment after final received on 03/02/2004, applicant refer to pages 4-5 and the drawings for antecedent basis. However, the drawings and the referenced pages disclose "a ported nozzle" not "without a ported nozzle". In addition, the rest of the specification and the drawings do not teach such a limitation.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 33, line 9; applicant uses the phrase "without a ported nozzle", however the meaning of such a limitation is not understood since the specification and the drawings do not disclose such a teaching. Does the applicant intend to mean gas injection pins? Clarification is needed to understand what this phrase mean. In examining this claim, the examiner considers such a limitation to mean a gas injection pin.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 4-7, 15, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203).

With respect to claims 1 and 15, McGowan, Jr. discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization. Further, McGowan, Jr. teaches the following: a device to form a housing in a first web (col.3, lines 27-29), an article

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loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station for sterilizing a medical article inside the housing (col.3, lines 53-55), and sealing the medical article within the housing (col.4, lines 5-9). In addition McGowan, Jr., teaches that it is known in the art of sterilizing medical articles to precondition such articles in a pretreatment area by applying steam (col.1, lines 28-34) prior to sterilizing them. Thus, it would have been obvious to one having ordinary skill in the art to modify the method and the apparatus of McGowan, Jr. to include a preheating step since such a step results in increasing the sterilizing effects of ethylene oxide (col.1, lines 36-44).

With respect to claims 4-5 and 19, McGowan, Jr. discloses the following: the sterilization-sealing station includes a steam source (col.3, lines 38-46), it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), and the pretreatment area has a steam supply (col.1, lines 28-33).

With respect to claims 6-7 and 20-21, McGowan, Jr. discloses the following: it is known in the art for the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is known in the art to be intrinsic to maintain the pressure in the housing (col.1, lines 52-53). In addition, in the art it is known that a controller is intrinsic to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 18, McGowan, Jr. discloses injecting steam into the housing (col.10, lines 61-64).

8. Claims 2-3, 8-14, 16-17, and 22-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGowan, Jr. (U.S.P.N. 5,749,203) in view of Multivac Packing Machines (IDS).

With respect to claims 8, 22, and 33, McGowan, Jr. discloses a device (figure 1, 10) and a method (col.1, lines 5-9) for article sterilization including the following: a device to form a housing in the first web (col.3, lines 27-29), an article loading station (col.3, lines 25-27), an alignment device (col.3, lines 38-42), a sterilization-sealing station where the article is sterilized by injecting gas between the first and second webs using injection nozzles (figure 4D), and then sealing the housing (col.4, lines 5-9). However, McGowan, Jr fails to teach injecting gas by using pins. The disclosure of the Multivac Packing Machines teaches injection by using pins (advantages column). Thus, it would have been obvious to one having ordinary skill in the art to modify McGowan, Jr method and device to include gas injection pins in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated (column 1, lines 5-10).

The features of claims 2, 16-17, 23, and 35-36 have been addressed above with respect to claims 8, 22, and 33.

With respect to claims 3, 9, and 24, McGowan, Jr. teaches injecting steam into the housing between the first and second webs (figure 4D and col.10, lines 52-53) and the injected steam pressurizes the housing to a pressure of 60 to 100 Psia (col.10, lines 54-55).

With respect to claims 10 and 29, McGowan, Jr. discloses that it is known in the art of sterilizing medical articles to have a pretreatment area for heating such articles (col.1, lines 28-33).

With respect to claims 11 and 28, McGowan, Jr. teaches that both the bottom and the top webs are formed of a gas permeable material (col.3, lines 29-31).

With respect to claim 12, McGowan, Jr. teaches the following: it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58) and the prior art teaches that the pretreatment area has a steam supply (col.1, lines 28-33) to supply moisture to the medical articles.

With respect to claims 13-14, McGowan, Jr. discloses the following: it is known in the art that the sterilization-sealing station includes a vacuum (col.1, lines 50-53) and a controller such that a controller is intrinsic to maintain the pressure in the housing (col.1, lines 52-53). In addition, it is known in the art that a controller is intrinsic to maintaining the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

With respect to claim 25, McGowan, Jr. teaches evacuating the housing before pressurizing with steam (figure 4C). With respect to evacuating the housing after pressurizing with steam, McGowan teaches that after removing the supply of steam then the sterilizing gas is introduced (col.10, lines 64-65). However, since the housing is not sealed yet; removing the supply of steam would inherently result in steam moving out of the housing and in reducing the pressure within the housing.

With respect to claim 26, even though McGowan, Jr. does not explicitly teach of a time period of maintaining the housing with steam, certainly some time interval is needed to reach the specified steam pressure within the housing (col.10, lines 62-64).

With respect to claim 27, McGowan, Jr. teaches pressurizing the housing with steam and with sterilizing gas within a form, fill and seal device (10) having sterilization-sealing station (410). With regard to the Btu values, even though McGowan does not explicitly disclose such values, however, McGowan pressurizes the housing with steam to a pressure of 80 Psia such that McGowan is delivering energy that falls within the Btu value range.

With respect to claims 30-32, McGowan, Jr. discloses the following: it is known in the art that sterilization and sealing are conducted at a sterilization-sealing station (col.2, lines 42-58), the sterilization-sealing station includes a steam source (col.3, lines 38-46), it is known in the art that substantially no moisture is supplied to the medical articles at the sterilization-sealing station (col.2, lines 42-58), the pretreatment area has a steam supply (col.1, lines 28-33), it is known in the art that the sterilization-sealing station includes a vacuum (col.1, lines 50-53), it is known in the art to maintain the pressure in the housing (col.1, lines 52-53), and it is also known to maintain the pressure in the housing as to allow the relative humidity to be at least 40% during sterilization gas exposure (col.2, lines 57-67).

The features of claim 34 have been addressed above with respect to claims 1 and 15.

Response to Arguments

9. Applicant's arguments with respect to claims 1-36 have been considered but are moot in view of the new ground(s) of rejection.

On page 10 of the response applicant argues that, "The '203 therefore teaches away from preheating when using a first web into which a housing is formed, a second web that is aligned with the first web, which first and second webs are sealed after sterilization". The examiner disagrees. The invention in the '203 reference teaches preheating the article within the housing by applying steam then injecting sterilant. So, the '203 reference does not teach away from preheating. Also, the '203 reference teaches that it is known to preheat articles in preheating chambers. Thus, it would have been obvious to one having ordinary skill in the art to modify the method and the apparatus of McGowan, Jr. to include a preheating step since such a step results in increasing the sterilizing effects of ethylene oxide (col.1, lines 36-44).

On pages 11-12 of the response, applicant argues that, "On the other hand, the '203 patent is directed to a very different application, namely sterilization of medical articles". The examiner disagrees. The Multivac reference is a part of a form-fill-and seal device as is the instant application such that insuring that air does not enter into packages by substituting one injection means for another is obvious to one having ordinary skill in the art of sterilization.

Conclusion

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 8:30-5:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Monzer R. Chorbaji *MRC*
Patent Examiner
AU 1744
06/25/2004

Krisanne Thornton
KRISANNE THORNTON *ASTR2A13*
PRIMARY EXAMINER